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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,913	12/06/2005	Giora Amitzur	30028	6778

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ARLINGTON, VA 22215

EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

MAIL DATE	DELIVERY MODE
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08/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,913

Applicant(s)

AMITZUR ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-44 and 56-59 is/are allowed.
- 6) ☒ Claim(s) 45, 48-50, 52-55 is/are rejected.
- 7) ☒ Claim(s) 46, 47 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Arguments

2. Applicant's arguments, see the remarks and amendment filed 30 May 2007, with respect to claims 1-44 have been fully considered and are persuasive. The rejection of claims 1-44 has been withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 45, 48, 50, and 52-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Sharrock (US Patent 6994675).

Regarding claims 45 and 48, Sharrock teaches a method of determining endothelial dependent vasoactivity comprising applying a stimulus to a blood vessel (occlusion), measuring a pulse wave velocity in the vessel (column 2, lines 35-37,

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determining an autonomic nervous system activity of the subject (column 12, lines 61-67), correlating the pulse wave velocity to the ANS activity to obtain a correlation function having an index (arterial compliance – column 3, lines 62-63), and displaying the indication (figures 9, 10). The examiner notes that applicant has included the limitation "...if the index has a predetermined value..." – since this limitation is not required, it has not been further treated.

Regarding claim 50, Sharrock further discloses performing the measurements over a brachial artery (column 9, lines 20-21).

Regarding claim 52, Sharrock further discloses determining heart rate variability of the pressure-related signals (column 4, lines 44-60).

Regarding claim 53, Sharrock further discloses recording electrocardiogram signals as part of determining ANS activity (column 10, lines 14-17).

Regarding claim 54, Sharrock further discloses using piezoelectric ceramic element sensors (column 3, lines 2-3).

Claim Rejections - 35 USC § 103

5. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharrock in view of Sugo (US Patent Application Publication 2002/0151805).

Sharrock discloses all the elements of the claimed invention, as described above, except for the stimulus comprising temperature reduction. Sugo teaches a method of measuring a pulse wave velocity following application of a stimulus, where the stimulus may be temperature reduction (paragraphs [0009]). It would have been obvious to one

of ordinary skill in the art at the time the invention was made to have made the system of Sharrock using temperature reduction as the stimulus, as taught by Sugo, since temperature reduction is well-known in the art as a stimulus for pulse volume measurements.

6. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sharrock in view of Schnall (US Patent 6461305).

Sharrock discloses all the elements of the claimed invention, as described above, except for the sensor being a membrane-based sensor. Schnall teaches a pulse wave monitor that uses a membrane-based sensor (column 9, lines 29-34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a membrane based sensor, as taught by Schnall, with the system of Sharrock, since it is merely the substitution of one sensor for an equivalent.

Allowable Subject Matter

7. The following is an examiner's statement of reasons for allowance:

The prior art of record fails to anticipate or make obvious the inventions of claims 1-44 and 56-59, including, *inter-alia*, determining endothelial dependent vasoactivity by recording pressure-related signals and extracting two parameters sensitive to arterial radius, one at the onset of dilation and the second at a later stage of dilation, and using the parameters to determine a characteristic change of the blood vessels's function, which is in turn used to determine the subject's endothelial dependent vasoactivity.

Schnall (US Patent 6939304) discloses a method of determining endothelial dependent vasoactivity from pressure-related signals and their associated parameters, but does not disclose extracting parameters relating to two stages of arterial dilation from the pressure signals.

8. Claims 46, 47, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of claim 46 including, *inter-alia*, determining endothelial dependent vasoactivity by applying a stimulus to a vessel, measuring pulse wave velocity in the vessel, determining the subject's autonomic nervous system activity, correlating the PWV and ANS activity in an index, where when the index meets a predetermined value applying a second stimulus to a different blood vessel and measuring its PWV and ANS to determine the subject's endothelial-dependent vasoactivity.

The prior art of record fails to anticipate or make obvious the method of claim 47 including, *inter-alia*, determining endothelial dependent vasoactivity by applying a stimulus to a vessel, measuring pulse wave velocity in the vessel, determining the subject's autonomic nervous system activity, correlating the PWV and ANS activity in an index, where when the index meets a predetermined value applying a second stimulus to a blood vessel and measuring its PWV and ANS to determine the subject's

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endothelial-dependent vasoactivity, where the stimuli may be thermal, chemical, electrical, mental stress, or physical exercise.

The prior art of record fails to anticipate or make obvious the method of claim 47 including, *inter-alia*, determining endothelial dependent vasoactivity by applying a stimulus to a vessel, measuring pulse wave velocity in the vessel, determining the subject's autonomic nervous system activity, correlating the PWV and ANS activity in an index, where when the index meets a predetermined value applying a second stimulus to a different blood vessel and measuring its PWV and ANS to determine the subject's endothelial-dependent vasoactivity, where the second vessel is one of brachial, radial, or carotid arteries.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2003/0036685 to Goodman, which discloses a similar invention.

US Patent Application Publication 2006/0195035 to Sun, which discloses a similar invention.

US Patent Application Publication 2007/0123787 to Kitajima, which discloses a similar invention.

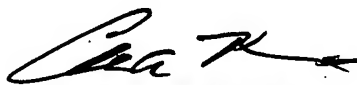
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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